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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,122	02/14/2002	Dale Clifford	6005.019	8896

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DREIER & BARITZ LLP
499 PARK AVENUE
20TH FLOOR
NEW YORK, NY 10022

EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,122	CLIFFORD ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/18/02* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it contains the phrases "The present invention" and "another embodiment of the invention". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "210" has been used to designate both **vertebrae**, on page 7, line 5, and page 8, line 2, and **depression**, on page 9, line 26 and page 10, lines1, 7. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "200" has been used to designate both **lobe**, shown in figures 12-16 and disclosed on page 9, lines 26, 29, and page 10, lines 7, 11, and **bone**, shown in figure 6. A proposed drawing correction or corrected drawings are required in reply to the Office action to

avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 20 and 160. No reference numerals disclosed in the specification are shown in figures 11a and 11b. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 65, shown in figure 4. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

It is also noted to the applicant, that in figure 5b, both the inner and outer sleeve have been designated as "20", wherein the inner sleeve should be 22.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 14, 15, 17-19, 22-23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Referring to claim 15, applicant has positively claimed a portion of the body. It is suggested to change "occupies the disc space between two vertebrae" to recite --is configured to occupy a disc space between two vertebrae--. Referring to

claims 22 and 23, these claims have preambles that are not consistent with the independent claim 1 preamble. The scope of the claim, set in the preamble should not be changed. Also, it is noted that the scope of claim 1 is a product claim, not a method claim. Claims 22 and 23 should be changed to "The orthopedic implant of claim 1,".

Claim 5 recites the limitation "the walls" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the openings" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the design" in line 6. There is insufficient antecedent basis for this limitation in the claim. Claims 18-19 depend upon claim 17 and inherit all problems associated with the claim.

Claim 19 recites the limitations "the perforations" and "the ends" in lines 2 and 3 respectively. There is insufficient antecedent basis for these limitations in the claim.

Claim 24 recites the limitations "the sheet" and "the design" in lines 4 and 6 respectively. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 15 and 22 positively claims portions of the body, specifically, two vertebrae, which non-statutory subject matter. It is suggested to the applicant to

incorporate language such as "configured to be placed" or "shaped to be implanted" into the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 8, 10, 11, 13, 15, 16, 22, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson (Pub. No. US 2003/0149484 A1). Michelson discloses an orthopedic implant (100) comprising a foraminous (130), corrugated (132) biocompatible titanium material (0102) formed into a sleeve (120) provided with first (122) and second (124) open ends and a

length between, the implant provided with lobes (tips of 132) and depressions (spaces between 132). Michelson discloses an implant (100) constructed from a foraminous (130) corrugated (132) loop (fig.4, 6). Michelson discloses an implant (100) comprised of an intersecting network of landed regions defining a plurality of openings (130) in the network, wherein the implant has a substantially circular shape (fig.4, 6). Michelson discloses an implant that surrounds a bone graft or bone growth promoting material (0045). Michelson discloses an implant (100) that occupies the space between two vertebrae (0006). Michelson discloses an inner (120) and outer sleeve (110).

Claims 1-3, 8, 10, 11, 13, 15, 22, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb et al. (USPN 6,503,279 B1). Webb discloses an orthopedic implant comprising a foraminous (7 or pores), corrugated (3-dimensional surface texture 9) biocompatible material formed into a sleeve (hollow cylinder, col.3, lines 8-10) provided with first (1) and second (2) open ends and a length between, the implant provided with a plurality of lobes and depressions (9). Webb discloses an implant constructed from a foraminous (7, pores) corrugated (9) loop (cylinder, fig.1). Webb discloses an implant comprised of an intersecting network of landed regions that define a plurality of openings (7, pores) in the network, wherein the implant has a substantially circular shape (fig.1). Webb discloses an implant to occupy the space between two vertebrae (col.3, lines 8-9). Webb discloses an implant that surrounds a bone graft or bone growth promoting material (col.2, lines 18-21).

Claims 1-4, 8, 10, 12, 13, 15, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Knothe et al. (USPN 6,143,031). Knothe discloses an orthopedic implant comprising a foraminous (8, 12), corrugated (7, 9) biocompatible titanium material (col.2, lines

32-34) formed into a sleeve (1) provided with first (right end) and second (left end) open ends (fig.1) and a length between, the implant provided with lobes (area between grooves 7) and depressions (grooves 7). Knothe discloses an implant constructed from a foraminous (8, 12) corrugated (7, 9) loop (fig.1). Knothe discloses an implant comprised of an intersecting network of landed regions (surface) defining a plurality of openings (8, 12) in the network, wherein the implant has a substantially elliptical shape (fig.1, 2). Knothe discloses an implant that surrounds a bone graft or bone growth promoting material (col.1, lines 59-61). Knothe discloses an implant that occupies the space between two vertebrae (col.1, lines 6-8).

Claims 1, 3, 8, 10, 12, 15, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Weiland et al. (USPN 6,371,987 B1). Weiland discloses an orthopedic implant comprising a foraminous (4, 5), corrugated (outer surface of 1, 2, 3) biocompatible material formed into a sleeve (fig.1), wherein the implant is provided with a plurality of lobes (peak of 1, 2, 3) and depressions (connecting area of 1, 2, and 3) and is constructed from a foraminous (4, 5) corrugated (outer surface 1, 2, 3) loop (fig.1). Weiland discloses an implant comprised of an intersecting network of landed regions (surface) that define a plurality of openings (4, 5) in the network, wherein the implant has a substantially elliptical shape (fig.1). Weiland discloses an implant occupying the space between two vertebrae (fig.5).

Claims 1-4, 6-8, 10, 12, 13, 15, 22, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Biscup (USPN 6,245,108 B1). Biscup discloses an orthopedic implant (10) comprising a foraminous (140, 150, 160), corrugated (80) biocompatible titanium material (col.3, lines 61-63) formed into a sleeve (12) having first (20) and second (30) open ends and length between, wherein the implant (10) is provided with a plurality of lobes (ridges 80) and

depressions (space between ridges 80). Biscup discloses an implant (10) having four and six lobes and depressions (80, see fig.2, 3), wherein the implant (10) is constructed of a loop (12). Biscup discloses an implant (10) comprised of an intersecting network of landed regions (surface) that define a plurality of opening (140, 150, 160) in the network, wherein the implant (10) has a substantially elliptical shape (fig.1). Biscup discloses an implant (10) surrounding a bone graft or bone growth promoting material (300, col.5, lines 17-21; fig.4). Biscup disclose an implant that occupies the space between two vertebrae (col.3, lines 30-32; fig.5).

Claims 1-3, 5, 9-11, 14, 17-19, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Lemperle et al. (USPN 6,391,059 B1). Lemperle discloses an orthopedic implant (42) comprising a foraminous (46), corrugated (col.14, lines 52-67; col.15, lines 1-25; col.16, lines 55-63) biocompatible material formed into a sleeve (fig.7, 8) having first and second open ends and provided with a plurality of lobes (protrusions) and depressions (indents, col.16, lines 55-65). Lemperle discloses an implant having walls with a thickness of about 0.5 to 3.0mm (col.6, lines 44-45). Lemperle discloses an implant constructed from a foraminous (46) corrugated sheet (fig.3a), wherein the implant is comprised of an intersecting network of landed regions (44) that define a plurality of opening (46) in the network, and the implant has a substantially circular shape (fig.7, 8). Lemperle discloses a cerclage (suture) passing through the opening and secured around the sleeve (col.7, lines 16-22). Lemperle discloses a method of providing an orthopedic implant comprising providing a sheet (42), selecting the shape, size and position (col.8, lines 55-65) of openings (46) and corrugations (col.14, lines 52-67; col.15, lines 1-25; col.16, lines 55-65), selecting a material, forming the sheet and enclosing it to form the implant (fig.4, 7, 8). Lemperle discloses encircling an area of bone with the sheet to form a

sleeve and securing the sheet around bone (fig.4, 7, 8) by threading a cerclage (suture) through the perforations and corrugations and affixing the ends of the cerclage (suture, col.7, lines 12-22).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER